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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,213	10/31/2003	Martin T. Gerber	P0011667.00	1507
27581	7590	10/19/2007		
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MINNEAPOLIS, MN 55432-9924			EXAMINER SMITH, RUTH S	
			ART UNIT 3737	PAPER NUMBER
			MAIL DATE 10/19/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/698,213

Applicant(s)

GERBER ET AL.

Examiner

Ruth S. Smith

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 21, 2007 has been entered.

***Claim Objections***

Claims 15,17,18 objected to because of the following informalities: In claims 15,17 "the second actuator" lacks antecedent basis. In claim 18, recitation of "a second actuator" is confusing" in that "a first actuator" has not been set forth. Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3,5-7,9-18,20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desai in view of Clement et al (5,368,045) or Sarnoff et al (4,226,235) and Lemelson (4,578,061). Desai discloses a method and apparatus for delivering a therapeutic agent and surgical tool to the diseased or injured site by imaging the target location such as prostate gland with ultrasound imaging device as shown in figure 3. The surgical tool or device can either be introduced noninvasively via body cavity or invasively via insertion needle where the needle insertion is through the perineum where the treatment fluid, i.e. therapeutic agent such as denervating agent is introduced to the patient. The ultrasound imaging probe 36 provides feedback to verify the location of the needle placed in the patient to deliver the therapeutic agent to desired location. Desai further discloses the secondary reservoir inasmuch as figure 2 shows that the syringe 34 is interchangeable to provide multiple therapeutic agent injection from multiple syringes. Desai fails to disclose the use of a spring-loaded needle or the passage of the needle through a side of a shaft. The use of spring-loaded needles in the art are old and well known as seen for example in Clement et al and Sarnoff et al. It would have been obvious to one skilled in the art to have modified Desai such that the needle used is a spring-loaded needle. Such a modification merely involves the substitution of one known type of needle for another. The advantage of a spring-loaded needle in the apparatus of Desai would be that it would allow for more efficient and effective actuation of the needle into tissue as taught by Clement et al or Sarnoff et al. Lemelson discloses an injection catheter where the needle can extend outside the catheter shaft via an opening on the side of the shaft where the needle would then penetrate tissue. It would have been obvious to one skilled in the art to have further modified Desai such that the needle passes through a side of the shaft and then extends through the tissue. Such a modification involves the substitution of one known injector arrangement for another. It would have been obvious to one skilled in

the art that such a modification would yield a predictable result of allowing the needle to penetrate tissue not easily accessible at the distal end of the device.

Claims 4, 8, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desai in view of Clement et al (5,368,045) or Sarnoff et al (4,226,235) and Lemelson (4,578,061) as applied to claim 1, 7, and 11 above, and further in view of Henley et al (US 6,477,410 B1). Desai is silent as to the use of botulinum toxin. This particular application of botulinum toxin to the prostate gland is well known in the art as seen in Henley et al where the botulinum toxin is applied to prostate gland for therapy. Therefore, it would have been obvious to one of ordinary skill in the art to have applied the teachings of Henley et al's botulinum toxin injection to prostate gland to the method and apparatus of Desai's image feedback guidance to accurately deliver the botulinum toxin to the prostate gland.

Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desai in view of Clement et al (5,368,045) or Sarnoff et al (4,226,235) and Luther et al (7,037,294). Desai discloses a method and apparatus for delivering a therapeutic agent and surgical tool to the diseased or injured site by imaging the target location such as prostate gland with ultrasound imaging device as shown in figure 3. The surgical tool or device can either be introduced noninvasively via body cavity or invasively via insertion needle where the needle insertion is through the perineum where the treatment fluid, i.e. therapeutic agent such as denervating agent is introduced to the patient. The ultrasound imaging probe 36 provides feedback to verify the location of the needle placed in the patient to deliver the therapeutic agent to desired location. Desai further discloses the secondary reservoir inasmuch as figure 2 shows that the syringe 34 is interchangeable to provide multiple therapeutic agent injection from multiple syringes. Desai further discloses the use of a transurethral sheath. Desai fails to disclose the use of a spring-loaded needle or a wheel used to rotate the orientation of the needle. The use of spring-loaded needles in the art are old and well known as seen for example in Clement et al and Sarnoff et al. It would have been obvious to one skilled in the art

to have modified Desai such that the needle used is a spring-loaded needle. Such a modification merely involves the substitution of one known type of needle for another. The advantage of a spring-loaded needle in the apparatus of Desai would be that it would allow for more efficient and effective actuation of the needle into tissue. Luther et al disclose a needle having a wheel which permits rotation of the needle to a desired orientation. It would have been obvious to one skilled in the art to have further modified Desai such that the spring-loaded needle includes a wheel to rotate the needle to a desired orientation. Such a modification allows to needle to be located more precisely in the target tissue as desired. The modified device of Desai would be capable of permitting rotation of the needle while in the shaft.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

This is a provisional obviousness-type double patenting rejection.

Claims 1-24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27-47 of

copending Application No. 10/698,676 in view of Lemelson . Although the conflicting claims are not identical, they are not patentably distinct from each other because with respect to claims 1-21 of the present application, the claims involve an obvious broadening of the claims in application serial no. 10/698,676. Furthermore, as taught by Lemelson, it is known to have a needle pass through a side of a catheter shaft or parallel to the longitudinal axis of the shaft. With respect to claims 22-24 of the present application, the specific type of mechanism used to position the needle at the correct orientation would have been obvious to one skilled in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.


### ***Response to Arguments***

Applicant's arguments with respect to claims 1-24 have been considered but are moot in view of the new ground(s) of rejection. With respect to claims 22-24, Luther et al discloses an embodiment where rotation of the spring barrel adapter allows rotation of the needle to a desired rotation (see column 3, lines 62-67, -column 4, lines 1-3). The modified device of Desai would be capable of permitting rotation of the needle while in the shaft.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S. Smith whose telephone number is 571-272-4745. The examiner can normally be reached on M-F 7:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Ruth S. Smith  
Primary Examiner  
Art Unit 3737

RSS